



**GUIDANCE DOCUMENT FOR REQUEST FOR EXEMPTION
OF SELECT AGENTS AND TOXINS FOR PUBLIC HEALTH OR
AGRICULTURAL EMERGENCY OR
INVESTIGATIONAL/EXPERIMENTAL PRODUCT**

FORM APPROVED
OMB NO. 0579-0213
OMB NO. 0920-0576
EXP DATE 01/31/2006



INTRODUCTION

The "Public Health Security and Bioterrorism Preparedness and Response Act of 2002" (Public Law 107-188: June 12, 2002) requires that the United States improve its ability to prevent, prepare for, and respond to bioterrorism and other public health emergencies. It necessitates that individuals possessing, using or transferring agents or toxins deemed a severe threat to public, animal or plant health, or to animal or plant products, notify either the Secretary of the Department of Health and Human Services (HHS) or the Secretary of the Department of Agriculture (USDA). Subsequent to enactment of this law, requirements for possession, use, and transfer of select agents and toxins were published by HHS (42 CFR 73) and by USDA (7 CFR 331 and 9 CFR 121).

Responsibility for providing guidance on this form was designated to the Centers for Disease Control and Prevention (CDC) by the Secretary, HHS, and to the Animal and Plant Health Inspection Service (APHIS) by the Secretary, USDA. In order to minimize the reporting burden to the public, APHIS and CDC have developed a common reporting form for this data collection. This form (APHIS/CDC Form 5) is designed to assist entities in complying with this legal obligation.

This form should be used to apply for exemption from the requirements of 7 CFR 331, 9 CFR 121, or 42 CFR 73 in cases of: (a) Use of an investigational product, or, (b) Due to public health or agricultural emergency. This exemption request should be sent to either APHIS or CDC, as appropriate, for exemption consideration. For HHS agents and toxins, the applicant should contact CDC (telephone: 404-498-2255; facsimile: 404-498-2265). For HHS/USDA overlap agents, the applicant should contact either APHIS or CDC. For USDA agents and toxins, the applicant should contact APHIS (telephone: 301-734-5960; facsimile: 301-734-3652). A listing of HHS select agents and toxins is available at <http://www.cdc.gov/od/sap>. A listing of USDA select agents and toxins is available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html.

NOTE: This form is not for use when applying for an exclusion. To apply for an exclusion of an attenuated strain of a select agent or toxin, an applicant must submit a written request and supporting scientific information to APHIS or CDC. Information in the written request should include at a minimum: strain, how strain was derived; how it is ascertained that it does not pose a severe threat to public health or to animal or plant health or to animal or plant products, and all citation or pertinent data to support your request.

INSTRUCTIONS

Entities may apply for an exemption from the requirements of 7 CFR 331, 9 CFR 121, or 42 CFR 73 using this form (1) If the entity possesses, uses, or transfers investigational or experimental products (IND) that are, bear, or contain select agents or toxins; or (2) In order to respond to a domestic or foreign public health or agricultural emergency.

All applicants must complete Section 1. Section 2 should be completed for those entities that wish to request an exemption due to investigational use of select agents or toxins. Section 3 should be completed for those entities that wish to apply for an exemption due to a public health or agricultural emergency. Applicants must sign and date the form.

OBTAINING EXTRA COPIES OF THIS FORM

To obtain additional copies of this form, contact APHIS at (301) 734-5960 or CDC at (404) 498-2255. This guidance document and form are also available at http://www.aphis.usda.gov/programs/ag_selectagent/index.html and <http://www.cdc.gov/od/sap>.

WHERE TO SEND THE COMPLETED FORM

Return completed forms to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 or Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Road NE, Mailstop E-79, Atlanta, GA 30333.



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Read all instructions carefully before completing the form. Answer all items completely and type or print in ink. The form must be signed and submitted document to: Agricultural Select Agent Program, 4700 River Road Unit 2, Mailstop 22, Cubicle 1A07, Riverdale, MD 20737 or Centers for Disease Control and Prevention, Select Agent Program, 1600 Clifton Rd NE, Mailstop E-79, Atlanta, GA 30333.

SECTION 1 – TO BE COMPLETED BY ALL APPLICANTS					
Entity name			Entity registration number (if applicable)		
Entity address (NOT a post office address)			City	State	Zip code
Applicant	Title	Telephone	FAX	E-mail	
Business Address (NOT a post office address)			City	State	Zip Code
Are you the: <input type="checkbox"/> Laboratory Director <input type="checkbox"/> Responsible Official <input type="checkbox"/> Other (specify):					
SECTION 2 – TO BE COMPLETED FOR INVESTIGATIONAL/ EXPERIMENTAL PRODUCT EXEMPTION					
FDA IND number	FDA product name	This product has been approved for Phase I clinical trials by FDA: <input type="checkbox"/> Yes <input type="checkbox"/> No			
USDA veterinarian product code number	USDA veterinarian product name	This product has been tested and approved for field trials by USDA: <input type="checkbox"/> Yes <input type="checkbox"/> No			
Investigational/ Experimental product (Give select agent name and characterization)					
Federal act that authorizes investigational use of this product					
Provide a detailed justification for exemption from registration for select agents and toxins due to investigational use. Provide sufficient detail to argue that applying additional regulation under 42 CFR 73, 9 CFR 121, or 7 CFR 331 (as applicable) would not be necessary to protect public health and safety (attach additional sheets if necessary):					
SECTION 3 – TO BE COMPLETED FOR PUBLIC HEALTH OR AGRICULTURAL EMERGENCY EXEMPTION					
INFORMATION ON PUBLIC HEALTH OR AGRICULTURAL EMERGENCY					
Name of person most familiar with public health or agricultural emergency				Telephone number	
Description of select agent(s) involved in public health or agricultural emergency					
Description of disease caused by select agent(s):					
Date of first confirmed cases	Number of cases biweekly	How diagnosis was made			
Laboratory that confirmed original diagnosis		Name, address and phone of laboratory director			
Describe circumstances of public health/ agricultural emergency (attach additional sheets if necessary):					

INFORMATION ON SELECT AGENTS AND TOXINS INVOLVED	
Location where work with specimens will be conducted:	Building: Room:
Biosafety level of laboratory	Name of Principal Investigator
Type of specimens that will be received: <input type="checkbox"/> Clinical/diagnostic (Specify from which species): _____ <input type="checkbox"/> Isolates (Specify how and when they will be characterized): _____ <input type="checkbox"/> Environmental (Specify): _____ <input type="checkbox"/> Other (Specify): _____	
Is this source expected to provide additional specimens? <input type="checkbox"/> Yes <input type="checkbox"/> No	
Anticipated quantity of specimens to be received:	
Anticipated time period to receive specimen (give estimated end date):	

I hereby certify that the information contained on this form is true and correct to the best of my knowledge. I understand that if I knowingly provide a false statement on any part of this form, or its attachments, I may be subject to criminal fines and/or imprisonment. I further understand that violations of 42 CFR 73, 9 CFR 121 or 7 CFR 331 may result in civil or criminal penalties, including imprisonment.

Signature of Applicant: _____ Typed or printed name of Applicant: _____

Title of Applicant: _____ Date: _____

Public reporting burden: Public reporting burden of this collection of information is estimated to average 1 hour per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. An agency may not conduct or sponsor, and a person is not required to respond to a collection of information unless it displays a currently valid OMB control number. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden to CDC/ATSDR Reports Clearance Officer; 1600 Clifton Road NE, MS D-24, Atlanta, Georgia 30333; ATTN: PRA (0920-0576).